REMARKS

Reconsideration of the application, as amended, is respectfully requested.

Claim 1 has been amended to incorporate the limitations of claim 3, without prejudice to filing a divisional or continuation application to cover subject matter not currently pursued. Accordingly, claim 3 has been cancelled without prejudice. In view of the incorporation of the claim 3 subject matter into claim 1, the dependencies of claims 4 and 5 have been changed to claim 1.

The written description rejection concerning lack of recitation of HPL or HGL in claim 1 appears to be moot in view of the above amendments.

With respect to the rejection of claim 4 based on lack of written description, the Office appears to read claim 4 as if it excludes the full length antibody sequences or antigen binding fragments of the sequence ID No. recited in claim 5. Claim 4 does not appear to exclude any other CDR sequences. Rather, claim 4 merely specifies the sequences from which CDR3 are selected. The Office points to no precedent which holds that it is unlawful or improper for an Applicant to specify in a dependent claim certain sequences, for example, preferred sequences.

The Section 112 rejection of claim 1 would appear to be moot in view of the amendment reciting specificity to human pancreatic lipases.

With respect to the Section 112, first paragraph (enablement) rejection of claim 4, concerning the preferred CDR3 sequences: on page 21, lines 29-32 of the application

as filed it is indicated that CDR3 is known to be the most important region for binding to the antigen. The undersigned has been informed that CDR3 has the highest variability.

Also with respect to the enablement rejection of claim 4, the undersigned has been provided the following from "Immunology for Medical Students," Nairn and Helbert, Mosby International Ltd., 2002: In the mammalian genome there are approximately 50 V_H, 25 D_H AND 5-6 J_H gene segments in the heavy chain locus (these are the human numbers). The D, or *diversity* segment, like the J segment (joining), encode amino acids in the third hypervariable region and/or complementarity determining region 3 (CDR3). So during the VDJ recombination process to generate antibody diversity, the undersigned has been informed, most of the diversity is found in the CDR3 region, which also has the most antibody-antigen interaction interface. It follows that when claiming HPL binding heavy chain variable domain antibodies, the sequence requirements of CDR3 for antigen recognition are much more strict than the sequence requirements for CDR1 or CDR2, which can be expected to be much more tolerant to variation. The "undisclosed" CDR1 and 2 portions, therefore, should not cause a lack of enablement. Limiting the claim to merely the specifically disclosed CDR1 and CDR2 regions would be unduly limiting the scope of protection.

As to the Section 103 rejection, the Office point to no teaching in Convents et al., WO 99/46300 that VHHs, while stable in the presence of surfactants, also 1) remaing stable in the gastrointestinal tract of a mammal, 2) retain their antigen binding capacity under these conditions, 3) that the antigen binding capacity and that the interaction of the lipase with the VHH also inhibits the lipase enzymatic activity under these conditions in vivo, 4) this despite the fact that the VHH lacks effector functions.

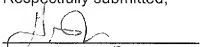
As to U.S. 6,558,936 Khldadoust et al., the Office points to no disclosure of compositons with lipase binding antibodies or indeed of antibodies, as opposed to antibodies that are in theory capable of merely recognizing a lipase antigen. Furthermore a distinction should be made between antibodies that can be used for detection purposes *in vitro* and antibodies that inhibit lipase activity *in vivo* under adverse conditions such as those in the gastrointestinal tract in a mammalian/human subject.

At column 23, lines 64 and onwards, U.S. 6,558,936 teaches that for therapeutic purposes human antibodies are particularly desirable. In striking contrast, the current invention is directed to therapeutic use of (*cameloid*) VHHS in the gastrointestinal tract deliverable by oral administration of food compositions or medicaments. Actually, U.S. 6,558,936 teaches away from the current invention to the extent that it proposes the use of human (classical) antibodies and hence implicitly points at administration in the bloodstream or tissue where an immune response against non-human antibodies (such as cameloid VHHs) could pose a threat to the treated subject.

As to the above and other references, even if the invention were obvious to try, that is not the standard for patentability.

In view of the foregoing, it is respectfully requested that the application, as amended, be allowed.

Respectfully submitted,



Gerard J. McGowan, Jr.
Registration No. 29,412
Attorney for Applicant(s)

GJM/pod
(201) 894-2297